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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,947	11/26/2003	Macghan Archambault	054630.0022	9626
7590 McCarter & English, LLP CityPlace I 185 Asylum Street Hartford, CT 06103-3495		06/26/2007	EXAMINER HANDY, DWAYNE K	
			ART UNIT 1743	PAPER NUMBER PAPER
			MAIL DATE 06/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/722,947	ARCHAMBAULT ET AL.
	Examiner Dwayne K. Handy	Art Unit 1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 November 2003.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-51 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/4/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____                          |

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## DETAILED ACTION

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13-17 and 29-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13 and 29 recite a "second locating indicia" on the first support member, but Applicant has *not recited a first locating indicia* in these claims.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 4-9, 20-28, 35-38, 49 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Devlin et al. (5,383,472). Devlin teaches a method and apparatus for handling tissue specimen. The apparatus include a flexible polyethylene bag (2) that may be sealed by a closure device (4) and a container (16) for holding the specimen.

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The container is best shown in Figure 2 and described in columns 5 and 6. The container has a first support member (16b) having a coating (absorbent member - #28) for holding the specimen and a second support member (16a) that extends from the first support member. As shown in Figure 2 and described in column 5, Devlin also includes a grid (26) for locating the specimen.

4. Claims 1, 4-9, 20-28 and 35-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Lary (4,993,056). Lary teaches a method and apparatus for handling tissue specimen. The apparatus include a flexible polyethylene bag (70) that may be sealed by a closure device (80) and a container (specimen board #10 and compression sheet #12) for holding the specimen. The container is best shown in Figure 1 and described in columns 5 and 6. The container has a first support member (board #10) having a coating (absorbent member - #22) for holding the specimen and a second support member (sheet #12) that extends from the first support member. As shown in Figure 2 and described in column 5, lines 24-44, Lary also includes an alphanumeric grid system for locating the specimen.

5. Claims 1, 4-9 and 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Russell (5,383,234). Russell teaches a method and apparatus for handling tissue specimen. The apparatus include a flexible plastic bag (12) that may be sealed by a closure device (16) and a holding device (tray #24) for holding the specimen. The holding device is best shown in Figures 1-3 and described in columns 3

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and 4. The holding device includes a coating for holding the specimen (see absorbent member disclosed in column 4, lines 37-51). Russell teaches a grid system having first (28) and second (32) locating grids. The second grid is comprised of a plastic that forms grooves in the holding tray (column 3, lines 46-64).

***Inventorship***

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 2, 3, 10-12, 19 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devlin et al. (5,383,472) in view of Miller et al. (5,671,983). Devlin teaches every element of claims 2, 3, 10-12, 19 and 39-42 except for a sealable bag having portions facing inward for handling contents inside the bag. Miller teaches a lockable storage bag having internally disposed hand covering elements. Miller teaches a wide variety of uses for their bag including handling food or tissue (Figures 1 and 7) and manipulation of equipment inside the bag (Figures 4 and 5). It would have been obvious to one of ordinary skill in the art to combine the bag of Miller with the device of Devlin. One would Devlin add the bag from Miller to the device of Devlin in order to manipulate collected biopsy specimen inside the bag while not touching the specimen. This would prevent contamination of the specimen or infection of the operator when preparing a sample for imaging.

9. Claims 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devlin et al. (5,383,472) in view of Russell (5,383,234). Devlin teaches every element

of claims 29-33 except for the second locating indicia. Russell teaches a tray for imaging a tissue specimen. The tray includes a first locating grid on one side and a second locating grid which generates a radiographic image of the grid on the opposite side. The second grid is in regulation with the first grid such that when a tissue sample is positioned on the first grid and exposed to X-rays, a radiographic image of the specimen superimposed on an image of the grid is produced. This allows for precise locating of any part of the specimen with respect to both grids (Abstract – column 3, lines 46-64). It would have been obvious to one of ordinary skill in the art to combine the second grid from Russell with the device of Devlin. One would add the second grid in order to superimpose the grid image onto the produced image as taught by Russell.

10. Claims 18, 34 and 43-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devlin et al. (5,383,472) in view of Marshall (5,694,882). Devlin teaches every element of claims 18, 34 and 43-48 except for the indicator element. Marshall teaches an indicator element for indicating when one has completed a task (i.e. taken a dose of medication). The embodiment of the device most relevant to the instant invention is shown in Figure 2 and described in column 4 lines 40-65. The indicator includes an arm (46) that is moved between indicia to indicate that a task has been completed. It would have been obvious to one of ordinary skill in the art to combine the indicator arm with the device of Devlin. One would add the indicator arm to show when a processing task has been completed for a particular collected specimen.

***Allowable Subject Matter***

11. Claim 51 is allowed.

The following is a statement of reasons for the indication of allowable subject matter: Claim 51 recites a method for storing and transporting a tissue specimen that is not taught or suggested by the cited prior art. The method includes use of a device having a first and second support member, first and second locating grids, a flexible bag for containing the support members and an indicator member.

***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hall (2004/0027036) teaches a bag having features for manipulating the contents inside the bag. Tobin (5,020,088) teaches a tissue location system. Goldsmith, Burke and Feldman show slide having locating grids.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DKH

June 20, 2007



JAN LUDLOW  
PRIMARY EXAMINER